

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 10/049,366	Applicant(s) TAKAHASHI ET AL.
Examiner JACQUELINE DIRAMIO	Art Unit 1641

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 October 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
 Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
 NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: _____.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641

Continuation of 11, does NOT place the application in condition for allowance because: of the reasons presented in the previous office action. Further, Applicant's arguments filed October 22, 2008 are not found persuasive. Applicant argues (see p10-12) that the combination of Burd et al. in view of Kileen et al. fails to render obvious Applicant's claimed invention because both Burd et al. and Kileen et al. prevent the passage of red blood cells into the remainder of the device as recited in Applicant's independent claim 1. In particular, Kileen et al. utilize an agent that comprises an inorganic salt that shrinks the red blood cells but does not let the cells pass through the overlay membrane. Burd et al. removes the red blood cells using a red blood cell binding reagent in order to provide a blood sample including no red blood cells. Although it may be apparent from the references that the Burd et al. and Kileen et al. references are attempting to remove red blood cells from the blood sample applied to their respective devices, it is further apparent that the combination of Burd et al. in view of Kileen et al. provides a device (biosensor) that contains all of the required structural and chemical elements of Applicant's independent claim 1. The Burd et al. reference includes all of the structural requirements of Applicant's claimed invention, except for the inclusion of a cell shrinkage reagent (i.e. crenating agent) within the carrier component. Kileen et al. provide a teaching of and motivation for including a crenating reagent within a test strip device, wherein the crenating agent comprises the same compound as recited in Applicant's claimed invention, i.e. an inorganic salt. Therefore, because the combination of Burd et al. in view of Kileen et al. results in the biosensor device of Burd et al. including the crenating agent of Kileen et al., the combination of Burd et al. in view of Kileen et al. contains all of the structural limitations and components of Applicant's claimed invention and provides motivation thereof, and thus renders Applicant's claims unpatentable and obvious. In addition, Applicant's recited limitation of "wherein the shrunk cell components of said liquid specimen permeate together with the liquid specimen into said reaction layer in a mixed state for analysis to occur" recites an intended use limitation, and because the combination of Burd et al. in view of Kileen et al. contains all of the structural and chemical requirements of Applicant's invention, the combination would expectly function in the same way and therefore would be capable of performing the recited intended use.